DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR § 1.114, including the fee set forth in 37 CFR § 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR § 1.114, and the fee set forth in 37 CFR § 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR § 1.114. Applicant's submission filed on 24 March 2008 has been entered.

2. The claims amendment filed 24 January 2008 has been entered as a matter of right. Applicants' arguments filed 24 January 2008 are addressed herein.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102.103

4. Claims 5, 7, 13, 15, 17 and 19 are rejected under 35 U.S.C. § 102(e) as anticipated by U.S. Patent 6,417,428 B1, Thomashow *et al* (filed 23 November 1998, claiming priority as a continuation-in-part to U.S. Applications 09/017,575 and 09/018,227 filed on 3 February 1998). A copy of U.S. Application 09/018,227 is attached hereto. This rejection has been modified from the rejection of record as set forth in the last Office action mailed 20 September 2007. Applicant's arguments filed 24 January 2008 have been fully considered but they are not persuasive. While the Shinozaki Declaration filed under 37 CFR § 1.132 has been considered, it is not deemed sufficient

to overcome subject matter covered by the instant rejection which would require a declaration under 37 CFR § 1.131.

Thomashow *et al* disclose a method of altering an environmental stress response of a plant by proving a recombinant molecule comprising a polynucleotide that encodes a polypeptide that has the amino acid sequence of Applicants' SEQ ID NO: 6, at claim 11 (SEQ ID NO: 2). Thomashow *et al* disclose a transgenic plant transformed with polynucleotide operably linked to a promoter that is regulated by changes in environment conditions at claim 8. Thomashow *et al* discloses SEQ ID NO: 1 that encodes SEQ ID NO: 2, SEQ ID NO: 2 being identical to Applicants' SEQ ID NO: 6. Thomashow *et al* disclose a plasmid comprising an rd29a gene promoter operably lined to a CBF1 coding region in Figure 17D and production of transgenic plants using said plasmid at columns 51-52. Thomashow *et al* disclose the rd29a gene promoter is a cis-acting cold-regulatory element in plants which has a 5 base pair core sequence of CCGAC, and that other promoters of similar function were known such as the cor6.6, kin1 and cor15a gene promoters (column 2, 2nd paragraph). Thomashow *et al* disclose that the rd29a promoter is induced by cold stress whereas the rd29b promoter could not be induced by low temperature (column 48, lines 6-9). Support under 35 USC § 112, first paragraph, for these limitations in Thomashow *et al* ('428 Patent) can be found in U.S. Application 09/018,227 to which the '428 Patent claims priority at page 2, 2nd paragraph and original claims 24 and 31.

Applicants argue that their claimed invention, as currently amended in claims 5-8 and as newly presented in claims 17-20 (as well as that set forth in new claims 13-16)

recites either a single promoter (claims 13-16) or a group of promoters (claims 5-8 and 17-20) that is/are distinctly yet unexpectedly different than the laundry list of promoters recited in Thomashow. Applicants argue that it is the uniqueness of the 5 claimed promoters that places them in their own category as to functionality and effectiveness and this grouping that includes the five named promoters or there membership of that unique group is simply nowhere disclosed or taught in any manner by Thomashow (page 7, 3rd paragraph of the Remarks). This argument is not found to be persuasive. Thomashow had disclosed operably linking the rd29a promoter to a CBF1 coding region and producing a transgenic plant as outlined above. Thomashow had also identified a subgenus of CCGAC containing promoters that could be used in the disclosed transgenic plant.

Applicants argue that *the* fact remains that this *grouping of promoters* and/or the *individual membership thereof as* set forth in Applicants' claims is a unique and distinct feature of Applicants' claimed invention that is simply not present anywhere in the text or figures of the Thomashow reference. Applicants argue that there is clearly no disclosure of dwarf resistant plant transformed by a DNA...operably linked downstream of a stress responsive promoter comprising DRE region(s) wherein the promoter is selected from a group of unique promoters having unexpectedly improved binding affinities resulting in a surprisingly improved response to environmental stresses and the resistance of dwarfism (page 7, 4th paragraph of the Remarks). This argument is not found to be persuasive. Failure of those skilled in the art to contemporaneously recognize an inherent property, function or ingredient of a prior art reference does not

preclude a finding of anticipation, Atlas Powder Co. v. IRECO, Inc., 190 F.3d 1342, 1349, 51 USPQ2d 1943, 1948 (Fed. Cir. 1999).

Applicants argue that the grouping of the 5 specialized promoters as well as their membership in such group is not disclosed in Thomashow. Applicants argue that the fact that the Thomashow approach results in a less favorable result is mentioned by Applicants as a classic example of secondary indicia of nonobviousness, namely the recognition of an existing problem and a need for improvement (page 8, 3rd paragraph of the Remarks). This argument is not found to be persuasive for the reasons given above. In addition, because the instant rejection has been modified the issue(s) of obviousness are now moot. But, to fully address Applicants' arguments, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Applicants argue that anticipation cannot hold because it no way does Thomashow disclose such a grouping based on the improved promoter performance that is characteristic of such group (page 8, 4th paragraph of the Remarks). This argument is not found to be persuasive, because Thomashow does disclose species that fall within the group of promoters recited in the claims.

Applicants argue that by way of argument and not admission, if all the elements of Applicants' invention are present in Thomashow and the claimed invention is anticipated and/or obvious as Examiner puts forth, it would have been expressly

disclosed since the overall subject matter of Thomashow is clearly conducive to such a rendering as the Thomashow inventors were obviously attempting to create the best environmental stress resistant plant known to them at the time (paragraph spanning pages 8-9 of the Remarks). Applicants argue that the inadequacy further highlights the *lack of disclosure* in Thomashow as to the claimed features of Applicants' invention, namely Applicants' unique grouping of the five claimed promoters and the membership thereof that is simply not disclosed or taught in any manner by Thomashow (page 9, 2nd paragraph of the Remarks). These arguments are not found to be persuasive. Thomashow does disclose the claimed features of Applicants' invention including at least 4 members of the genus of promoters, those being the rd29A gene promoter, the cor6.6 gene promoter, the cor15a gene promoter and the kin1 gene promoter; each of which contain at least one CCGAC core sequence, a cis-acting cold-regulatory element (a C-repeat/DRE region).

Applicants argue that Thomashow et al. teach away the use of stress responsive promoter comprising a DRE region to which said DREB1B protein can bind. Applicants argue that it is Applicants' use of the stress-responsive promoter enables DREB1B gene to amplify itself in response to environmental stress (self-amplification). Applicants argue that as a result of high level and stable expression of DREB1B gene in a short period of time, the transgenic plant acquires stress resistance without dwarfing. Applicants argue that at the time of filing of this application, it was not known what kind of promoters should be used for high level and stable expression of artificially introduced genes that activate only when the plant is subject to the stress. Applicants

argue that they found and demonstrated, for the first time in the world, that the self-amplification mechanism, i.e. the use of a promoter comprising DRE region, is useful for producing excellent stress resistant plants (page 11, 1st paragraph of the Remarks). These arguments are not found to be persuasive. Thomashow *et al* disclose that the rd29a promoter is induced by cold stress whereas the rd29b promoter could not be induced by low temperature (column 48, lines 6-9). Thomashow *et al* do not teach away from the claimed invention, but in fact direct one of skill in the art to choose a promoter that is induced by low temperature stress conditions.

Applicants argue that the present inventors recognized that the stress-responsive promoter did not cause the delay in growth or dwarfing of the plant, while the constitutive promoter, 35S promoter, caused the delay in growth or dwarfing of the plant. Applicants argue that the present inventors fully recognized the mechanism in which DREB genes enhanced the stress- resistance in a plant via stress-responsive promoter, therefore, they did not claim the use of rd29B promoter (page 12, 1st paragraph of the Remarks). This argument is not found to be persuasive. The fact that both Applicants and Thomashow *et al* teach away from use of the rd29B promoter, for different reasons, does not obviate a finding of anticipation.

Applicants argue that Thomashow et al. describe nothing about the stress-responsive promoter in the manner and to the degree present in the instant application nor did they have any idea about the merits of the stress-responsive promoter or they would have set forth a specialized grouping of the best promoters as did the present Applicants. Applicants argue that Thomashow et al merely set forth a laundry list of all

the promoters known as of the filing date of their application (page 12, 2nd paragraph of the Remarks). These arguments are not found to be persuasive. There no requirement that Thomashow et al had to recognize an inherent feature of the disclosed promoters.

Claim Rejections - 35 USC § 103

5. Claims 6, 8, 14, 16, 18 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thomashow *et al* (filed 23 November 1998, claiming priority as a continuation-in-part to U.S. Applications 09/017,575 and 09/018,227 filed on 3 February 1998). A copy of U.S. Application 09/018,227 is attached hereto.

The teachings of Thomashow *et al* are outlined above, and can be found in previous Office actions.

While SEQ ID NO: 1 of Thomashow *et al* is 94.1% identical to Applicants' SEQ ID NO: 5, SEQ ID NO: 1 of Thomashow *et al* teaches an identical coding region. The differences between SEQ ID NO: 1 of Thomashow *et al* and Applicants' SEQ ID NO: 5 does not appear to lead to a teaching of unexpected results since they are functionally equivalent.

The instant claims are *prima face* obvious in view of Thomashow *et al* because Applicants' SEQ ID NO: 5, and SEQ ID NO: 1 of Thomashow *et al* teach an identical coding region. One of ordinary skill in the art at the time of Applicants' invention would have known that modification of sequences outside of the coding region could be done as a matter of routine experimentation.

6. Claims 5-8 and 13-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thomashow *et al* (U.S. Patent 5,892,009, filed 4 September 1996) in view of Wang

et al 1995 (Plant Molecular Biology 28: 605-617), Baker *et al* 1994 (Plant Molecular Biology 24: 701-713) and Yamaguchi-Shinozaki *et al* 1993 (Molecular and General Genetics 236: 331-340).

Thomashow *et al* teach a DNA construct capable of transforming a cell comprising a nucleic acid sequence encoding SEQ ID NO: 2 at claim 24 and a cell transformed therewith at claim 49. Thomashow *et al* teach said DNA construct can further comprise an inducible promoter "(e.g., induce COR genes when a frost is imminent)" at column 14, lines 36-40. Thomashow *et al* teach that cis-acting cold-regulatory elements in plants were known that have a 5 base pair core sequence for CCGAC in all plant cold-regulated promoters that have been described to date, and identifies the cor15a promoter (Baker *et al* 1994), the cor6.6 and kin1 promoters (Wange *et al* 1995) and the rd29A promoter at column 1, line 59 to column 2, line 6.

Thomashow *et al* do not teach SEQ ID NO; 5, or any dwarfing effect by expressing a nucleic acid sequence encoding SEQ ID ON: 6 in a transgenic plant. While SEQ ID NO: 1 of Thomashow *et al* is 94.1% identical to Applicants' SEQ ID NO: 5, SEQ ID NO: 1 of Thomashow *et al* teaches an identical coding region. The differences between SEQ ID NO: 1 of Thomashow *et al* and Applicants' SEQ ID NO: 5 does not appear to lead to a teaching of unexpected results since they are functionally equivalent.

Yamaguchi-Shinozaki *et al* teach the rd29A promoter (see Figure 3A, page 335) and that the promoter is responsive to cold (see Figure 7, page 337).

It would have been *prima face* obvious to one of ordinary skill in the art at the time of Applicants' invention to modify the teachings of Thomashow *et al* to make a transgenic plant transformed with a DNA encoding Applicants' SEQ ID NO: 6 operably linked to any one of the cor15a, cor6.6, kin1 and rd29A promoters. Thomashow *et al* teaches that transforming a plant with a DNA encoding Applicants' SEQ ID NO: 6 would increase resistance to frost damage (see for example claims 37 and 38; see column 5, lines 31-40).

Conclusion

7. No claims are allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (571) 272-0799. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached at (571) 272-0975. The central FAX number for official correspondence is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (571) 272-1600.

/David H Kruse/
Primary Examiner, Art Unit 1638
4 June 2008